

**d.) Remarks.**

Applicant has canceled claims 3-6, 13, 30, 44, and 50, and amended claims 1, 11, 17, 28, 40, 41, and 51-54. The amendments to claims 1 and 11 are to limit the claims to consisting essentially of, from comprising. The amendments to claims 17, 28, 40, 41, and 47 are to conform to this language. The amendments to claims 51-54 are to insert the Deposit Accession number. Thus, no new matter is added and claims 1, 2, 7-12, 14-19, 21-29, 31-43, 45-49, and 51-54 are currently pending.

**Remarks Regarding 35 U.S.C. § 112, First Paragraph**

Claims 1-19 and 21-54 stand rejected, under 35 U.S.C. § 112, first paragraph, as allegedly not enabled. Applicant respectfully traverses this rejection.

Specifically, the Examiner objects to the use of certain strains of microorganisms as allegedly not available to the public. The Examiner kindly provides details to meet the deposit requirement set forth in 37 C.F.R. § 1.801-1.809.

As is set forth in the specification, the invention is directed to a composition and method that involves a specific treatment of microorganisms. The microorganisms which are involved with the claimed invention are varied and include a number of isolated classes, groups, genera, species, and strains, as well as certain marine microorganisms which the inventors isolated.

With regard to claims 1-19 and 21-50, Applicant respectfully notes that the microorganisms utilized in the application are all well-known and, corresponding, publicly available. For example, claims 9 and 49 refer to specific genera, claims 11 and 38 refer to specific groups, and claims 42 and 48 refer to specific strains. All of these microorganisms are publicly available and from a wide variety of sources. For example, Applicant invites the Examiner to review one of the most widely used sources of bacterial cultures, the American Type Culture Collection

(<http://www.atcc.org/CulturesandProducts/Microbiology/BacteriaandPhages/tabid/176/Default.aspx>).

Further, Applicant even went so far as to identify microorganisms obtained from commercial sources (e.g., see Specification, page 16, line 16). Thus, all of the microorganisms claimed by Applicant are commercially available and, accordingly, available to the public. The invention of these claims, and especially claims 9, 11, 38, 42, 48, and 49,

is therefore fully enabled. No more is required under Section 112 and Applicant respectfully requests that this rejection be withdrawn.

As noted above, the inventors also isolated certain marine microorganisms from a specific region of the Baltic Sea. Those organisms were identified in the specification by location collected as well as strain (see specification, page 15, lines 27-29; “Jasmunder Bodden [region] of the Baltic Sea”). This strain was identified as B30 and deposited with an International Depository in accordance with the Budapest Treaty. A copy of the Notice of Deposit indicating the Deposit Accession Number is attached. With regard to claims 51-54, Accession No. DSM 22930 has been added to these claims as appropriate. The invention of these claims is therefore fully enabled. No more is required under Section 112 and Applicant respectfully requests that this rejection be withdrawn.

Thus, the rejection of claims 1-19 and 21-54, under 35 U.S.C. § 112, first paragraph, is moot or overcome. Applicant respectfully requests that it be withdrawn.

#### **Remarks Regarding 35 U.S.C. § 112, Second Paragraph**

Claims 51-54 stand rejected, under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for including blank lines in the claims. Applicant respectfully traverses this rejection and has substituted the Deposit Numbers for the blank lines. This rejection is now moot and Applicant respectfully requests that it be withdrawn.

#### **Remarks Regarding 35 U.S.C. § 103(a)**

Claims 1-19 and 21-54 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Müller et al. (European Journal of Pharmaceutics; “Müller”) in view of Medina et al. (Biotechnology Advances; “Medina”), and Olaizola (Journal of Applied Biotechnology; “Olaizola”), and further in view of Kreitlow et al. (Journal of Biotechnology; “Kreitlow”) and Caudales et al. (International Journal of Systematic and Evolutionary Biology, “Caudales”). Applicant respectfully traverses this rejection.<sup>1</sup>

The Examiner alleges that Müller discloses “a biomass [is] in the form of microparticles (or nanoparticles), and the microparticles or nanoparticles of the biomass contain a pharmaceutical (or cosmetic) activity and said activity in non-bactericidal, said

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<sup>1</sup> Applicant respectfully incorporates herein all remarks made in Applicants prior responses with regard to the cited references.

microparticles or nanoparticles have a mean size of 10 nm to 10  $\mu$ m, the composition further comprising one or more additional pharmaceutically or cosmetically active substances" (Office Action, page 7). If the Examiner's recitation is correct, this is clearly not Applicant's claimed invention. As recited in the instant claims, and unlike Mueller, Applicant's claimed lipid composition contains no added pharmaceuticals or cosmetics. It is the treatment by which the microorganisms are exposed which results in the pharmaceutical activity. Nevertheless, Applicant has amended claim 1 to recite that the composition "consists essentially of" the listed elements. Thus, there is no added pharmaceutical, which is the exact opposite of the teachings of Mueller.

As shown in Examples 10, the microparticles obtained from the biomass, with no added pharmaceutical agent, were found to prevent transfer contamination with MRSA in the cow udder test. Similarly results were achieved with microparticles of the biomass, and again with no added pharmaceutical agent, in the model mouse ear test (Example 11), the pot belly pig test (Example 12), the skin model test (Examples 13-15), the prevention of skin transmission of MSRA (Examples 17 and 27), and the decontamination of MRSA populated mouse tails (Example 26). Thus, Mueller is a clear teaching against of Applicant's claimed invention and, thus, Mueller or Mueller in combination with another reference cannot render the claims obvious.

In view of all of Applicant's assertions above, the rejection of claims 1-19 and 21-54, under 35 U.S.C. § 103(a), is overcome or moot and Applicant respectfully requests that it be withdrawn.

**Conclusion**

The application is now in condition for allowance and a Notice of Allowance is respectfully requested. If any further issues arise with regard to the prosecution of this application, the Examiner is requested to telephone the undersigned as convenient.

Should additional fees be necessary in connection with the filing of this Response, or if a petition for extension of time is required, the Commissioner is hereby authorized to charge **Deposit Account No. 50-5044 for any such fees, referencing Attorney Docket No. 9015.002.US**; and applicant hereby petitions for any needed extension of time not otherwise accounted for with this submission.

Respectfully submitted,  
Remenick PLLC

Date: March 23, 2010

By

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Attached: International Forms DSMZ BP/4 and BP/1

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Nur für Patentzwecke!!  
Nicht für öffentliche oder Sicherheitshinterlegung!

## BUDAPESTER VERTRAG ÜBER DIE INTERNATIONALE ANERKENNUNG DER HINTERLEGUNG VON MIKROORGANISMEN FÜR DIE ZWECKE VON PATENTVERFAHREN

### ERKLÄRUNG BEI ERSTHINTERLEGUNG (REGEL 6.1)

Als  
DSMZ-DEUTSCHE SAMMLUNG VON MIKRO-  
ORGANISMEN UND ZELLKULTUREN GmbH  
Inkubstr. 7 B  
D-36124 Braunschweig

Von der Hinterlegungsstelle auszufüllen:  
DSMZ-Aufnahmesnummer

Eingangsdatum der Kultur:

### BAKTERIEN/ARCHAEEN/PILZE<sup>1</sup>

DER UNTERZEICHNETE HINTERLEGT DEN NACHSTEHEND BEZICHNETEN MIKROORGANISMUS AUFGRUND DES BUDAPESTER VERTRAGES UND VERPFLICHTET SICH, DIE HINTERLEGUNG WÄHREND DER IN REGEL 3.1 GENANNTEN DAUER NICHT ZURÜCKZUNEHMEN<sup>2</sup>

#### I. KENNZEICHNUNG DES MIKROORGANISMUS

Bezugszeichen<sup>3</sup>: B30 [*Anaerococcus cylindrica* B30 33]

Die zu hinterlegende Kultur ist:

(x) eine Reinkultur

{ } eine Mischkultur  
(max. zwei Komponenten)

Taxonomische Bezeichnung<sup>4</sup>: *Anaerococcus cylindrica*

#### II. ZÜCHTUNGSBEDINGUNGEN

Medium: BG 11 Medium siehe Anlage I

pH vor der Sterilisation

Sterilisation ZD min bei: 121 °C

pH nach Sterilisation: 7,5

Verhalten gegenüber Sauerstoff:

(x) aerob

{ } mikroaerophil

{ } obligat anaerob

Besondere Ansprüche an die Gasatmosphäre:  
keine

Bebrütungstemperatur: RT °C

Bebrütungsdauer:

Aufbewahrung bei: RT °C

Überimpfungsintervall: 4-6 Wochen

<sup>1</sup> Die DSMZ nimmt zur Hinterlegung ausschließlich Mikroorganismen an, die gemäß Biosecurity den Risikogruppen 1 und 2 zuzurechnen sind (vgl. 3735a (Technische Regeln für Biologische Arbeitsstoffe): "Einstufung von Bakterien in Risikogruppen" (TRBA 406) und Einstufung von Pilzen in Risikogruppen" (TRBA 409)). Gentechnisch veränderte Organismen müssen den Sicherheitsstufen S1 oder S2 entsprechend dem Gesetz zur Regelung der Gentechnik zugeordnet werden können.

<sup>2</sup> Dieses Formblatt kann auch verwendet werden, wenn der Unterzeichnete eine Hinterlegung eines Mikroorganismus, die er selbst oder sein Rechtsweghhaber außerhalb des Budapest-Vertrages bei derselben Hinterlegungsstelle vorgenommen hat, in eine Hinterlegung nach dem Budapest-Vertrag umwandelt. Es obliegt annehmlich, ob die Ersthinterlegung vor (Regel 6.4 Buchstabe d) oder nach dem Zeitpunkt stattgefunden hat, zu dem die Stelle den Status einer internationalen Hinterlegungsstelle erworben hat.

<sup>3</sup> Es wird dringend empfohlen, die taxonomische Bezeichnung und/oder die wissenschaftliche Beschreibung des Mikroorganismus (siehe unter VII.) anzugeben.

<sup>4</sup> Ankreuzen, wenn auf einem besonderen Blatt weitere Angaben eingebracht werden.

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE



INTERNATIONAL FORM

Ernst-Moritz-Arndt-Universität  
Greifswald

Fr.-L.-Jahnstr. 17  
17487 Greifswald

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT  
received pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITORY AUTHORITY  
identified at the bottom of this page

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: B30 (Bio33)	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: DSM 22930
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
<p>The microorganism identified under I. above was accompanied by:</p> <p>( ) a scientific description (x) a proposed taxonomic designation</p> <p>(Mark with a cross where applicable).</p>	
III. RECEIPT AND ACCEPTANCE	
<p>This International Depository Authority accepts the microorganism identified under I. above, which was received by it on 2009-08-12 (Date of the original deposit)</p>	
IV. RECEIPT OF REQUEST FOR CONVERSION	
<p>The microorganism identified under I above was received by this International Depository Authority on (date of original deposit) and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion).</p>	
V. INTERNATIONAL DEPOSITORY AUTHORITY	
<p>Name: DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH</p> <p>Address: Intheförste, 7 B D-38124 Braunschweig</p>	<p>Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s)</p> <p><i>V. Weh</i></p> <p>Date: 2009-09-11</p>

\* Where Rule 6 A (4) applies, such date is the date on which the status of international depository authority was acquired.

Form DSMZ-BP-4 (sole page) 08/2006